



PREPARING QUALITY & TECHNICAL IMPLEMENTING PROCEDURES

PROCEDURE ID: YMP-LBNL-QIP-5.2

REV. 1, MOD. 0

EFFECTIVE: 6/2/97

1. PURPOSE

This procedure describes the preparation and control of Yucca Mountain Project - Ernest Orlando Lawrence Berkeley National Laboratory (YMP-LBNL) quality implementing procedures (QIPs) and technical implementing procedures (TIPs) to ensure that procedures are (a) relevant, (b) the current revision, (c) correct, (d) reviewed and approved, (e) distributed to the places of work and accessible to those individuals needing them to perform work, and (f) assigned to responsible individuals for their care.

2. SCOPE

This QIP covers initiation, content and preparation, review and approval, changes to, and rescission of both quality and technical implementing procedures for YMP-LBNL.

QIPs describe specific rules for conducting and documenting quality-affecting activities in support of site-characterization tasks, and are written to implement the contractual requirements of the Quality Assurance Requirements and Description (QARD).

TIPs describe technical and scientific tasks that are repetitive, standardized, and could return different results should deviation from the sequence of steps occur. TIPs are written when such tasks are sufficiently complex to warrant a formal procedure. Less-complex tasks of this type are documented in notebook procedures, which are developed in accordance with YMP-LBNL-QIP-SIII.0. The Principal Investigator (PI), in consultation with the Engineering Assurance Manager (EA Manager), determines whether a TIP or notebook procedure is required.

3. PROCEDURE

3.1 Initiating Preparation of a Procedure

3.1.1 Any staff member working on YMP may propose preparation of a QIP to the EA Manager, or of a TIP to an appropriate PI.

3.1.2 For proposed QIPs, the EA Manager shall:

A. decide if a formal procedure is warranted;

B. decide if a DOE Yucca Mountain Administrative Procedure (YAP) or DOE Administrative Procedure (AP) should be directly followed, or if an YMP-LBNL QIP should be developed;

- C. explain the resolution to the requester; and
- D. refer unresolved issues to the Project Manager (PM) for final resolution.

3.1.3 For proposed TIPs, the PI shall:

- A. decide if a formal procedure is warranted;
- B. explain the resolution to the requester; and
- C. refer unresolved issues to the PM for final resolution.

Note. Documenting the actions of Section 3.1 is only required for a new QIP (or TIP) if the requester or EA Manager (or PI) deem it necessary. However, the rationale for developing a procedure shall be documented in Section 2, "Scope," of the procedure.

3.2 Content and Preparation of Procedures

3.2.1 The EA Manager shall assign a unique identifying number to each procedure, with input from the appropriate PI for TIPs. The EA Manager shall determine the level of detail and oversee the preparation and distribution of all QIPs. An appropriate PI shall determine the level of detail and oversee the preparation and distribution of each TIP.

3.2.2 Procedures shall be organized into ten Sections (or Topics). Headings that are not applicable shall be designated in the procedure as "None," "Not applicable," etc. These ten sections are:

1. **PURPOSE** - a summary statement of the procedure's objective;
2. **SCOPE** - a description of the general circumstances organization(s) and personnel to which the procedure applies, and (for QIPs only) the quality assurance requirements that it satisfies;
3. **PROCEDURE** - usually a step-by-step description of work, including prerequisites, limits, precautions, process parameters, technical and/or regulatory requirements, and environmental conditions. However, manuals, or procedures contained in manuals, may be included by reference so long as they are:
 - uniquely referenced (by document number, revision, etc.),
 - available at the work place, and
 - readily available to all potential users;

This section also includes, as appropriate, identification of quality verification and hold points, methods for demonstrating that the work was performed as required, and

associated activities and methods for altering the sequence of required activities.

4. **RECORDS MANAGEMENT** - a list of the lifetime and non-permanent records and controlled documents generated by the performance of the procedure;
5. **RESPONSIBILITIES** - specific statements defining critical positions, organizations and organizational interfaces responsible or necessary for the procedure's effective implementation;
6. **ACRONYMS AND DEFINITIONS** - a location for clarifying or defining terms, to help the reader understand the content of the procedure;
7. **REFERENCES** - a list of documents referenced in the procedure's text;
8. **ATTACHMENTS** - a list of supplementary information, forms, or other materials provided with the procedure;
9. **REVISION HISTORY** - a summary of the changes made to the procedure since the original version was issued, and specifying the impact of each change upon work activities and the reasons for the change where appropriate. The summary shall contain a dated synopsis for each change, and each synopsis shall specify which page(s) of the procedure were modified by the change; and
10. **APPROVALS** - a signature page, confirming the acceptable review of the procedure by the proper technical, engineering assurance, and management reviewers including quality assurance concurrence.

Additionally, each page of the procedure shall show the procedure's unique identifying number and revision number. The modification number for each page shall also be shown on the page, although different pages of the same procedure may have different modification numbers (see also Section 3.5.2).

3.3 Review and Approval of a Procedure

- 3.3.1 During the development process the Preparer shall deliver copies of initial and revised procedure drafts, supporting documents, and related materials to the EA Manager for his/her information. The originals of all completed reviews and review forms, the initial draft, and the final approved version shall be retained by the Preparer during the development process, and transferred to the YMP-LBNL Record Processing Center for storage after the approved procedure has entered service.
- 3.3.2 All new, revised and modified procedures shall undergo at least two technical reviews and one EA review by qualified individuals, selected by the PM based upon recommendations from appropriate

individuals. For QIPs, the EA Manager and the Preparer shall provide reviewer recommendations. For TIPs, the PI shall recommend the technical reviewers, and in consultation with the EA Manager shall recommend the EA reviewer.

If an organization other than YMP-LBNL will perform work under the proposed procedure or revision, then an appropriate person(s) representing that organization shall provide review comments on the procedure.

- 3.3.3 The reviewer(s) identified in paragraph 3.3.2 shall review the draft procedure according to YMP-LBNL-QIP-6.1 and return the YMP-LBNL Document Review/Comment Resolution (DRCR) form(s) and any editorial comments made on the draft to the Preparer for resolution.
- 3.3.4 Upon completion of this review, including resolution or incorporation of reviewer comments, the Preparer shall submit revised draft QIPs to the Office of Quality Assurance (OQA) Representative and revised draft TIPs to the OQA Representative and PI for review.
- 3.3.5 The OQA Representative shall perform a quality assurance (QA) review of the QIP or TIP according to YMP-LBNL-QIP-6.1, and return the DRCR form(s) and any editorial comments made on the draft to the Preparer for comment resolution.
- 3.3.6 For TIPs, the PI shall perform a technical and/or management review of the procedure, supply any comments, and return the draft procedure to the Preparer for comment resolution.
- 3.3.7 After resolution or incorporation of any technical reviewer and/or OQA Representative comments, the Preparer shall forward the revised draft procedure to the PM for final review.
- 3.3.8 The PM shall perform a management review of the procedure, and return it with any comments to EA Manager. The PM shall confer at this time with the EA Manager (for QIPs) and the PI (for TIPs) to determine when the procedure should be effective. The EA Manager (for QIPs), or the PI (for TIPs), shall assign the effective date to the procedure, based upon this discussion.
- 3.3.9 If the PM's review comments require changes to the procedure, the Preparer shall resolve or incorporate them into a final version of the document, as well as adding the effective date to the document header. The Preparer shall then route the original copy to all reviewers, via the EA Manager (or designee), for their approval or concurrence signatures in Section 10 of the procedure. Each reviewer shall sign and date, in dark ink, in the appropriate signature space.

The final signature shall be that of the PM. The procedure is then ready for distribution.

3.4 Distributing a Procedure

3.4.1 For QIPs only, the EA Manager or designee shall develop a new or updated draft requirements implementation matrix with the new revision of the procedure, and submit it for review. The reviewer shall review the matrix for accuracy, record any comments on YMP-LBNL DRCR form(s), return the draft matrix and forms to the EA Manager for comment resolution and upon comment resolution submit the final matrix to the Office of Civilian Radioactive Waste Management (OCRWM) Office of Quality Assurance for inclusion in the QARD requirements matrix database. The submitted input shall identify:

- A. where each applicable QARD requirement is addressed;
- B. where requirements are inapplicable, with justification for each inapplicability; and
- C. where exceptions to requirements have been taken, with justification for each exception.

3.4.2 The Document Control Staff shall provide for controlled distribution of procedures to the workplace.

3.4.3 The Document Control Staff shall update the active controlled documents list, and store superseded versions of such documents in a controlled manner.

3.5 Making Changes to an Active Procedure

If, while following an implementing procedure, work cannot be accomplished as described without producing an undesirable result, the personnel performing the work (or their supervisor) shall stop work. They shall, with supervisory input as appropriate, then determine what kind of changes must be made to the procedure prior to resuming work. Also, when changes to the QARD are made, the EA Manager shall evaluate whether changes to the QIPs are necessary, and shall initiate the change process when appropriate.

Three types of changes can be made to a QIP: editorial changes, modifications, and revisions. In addition to these types of changes, expedited changes can be made to TIPS.

3.5.1 Editorial Changes:

- A. include grammatical, spelling, and organizational title or numbering changes;
- B. are made by drawing a single line through the old text and adding any new text, the date, and the initials of the person making the change nearby;
- C. do not require a review, but are distributed to substitute the incorrect version of the document; and
- D. shall be approved by the organizational position responsible for the document and documented on a memo to file with the approval signature.

3.5.2 Modifications

Modifications are usually changes to a procedure that are minor or affect only one section of the procedure. Modifications shall be implemented by:

- A. preparing draft modified pages for the procedure and completing Attachment 1, "YMP-LBNL Procedure Modification Record," to summarize those modifications. **Note:** The first page of the procedure shall always be modified, even if the only change is an updated modification number in the header (per paragraph 3.5.2 E.), to indicate the most current revision and modification status for the document;
- B. obtaining reviews in accordance with Section 3.3 of this procedure;
- C. obtaining approval/concurrence signatures on the Modification Record from the EA Manager, OQA Representative and PM for QIPs, and EA Manager, OQA Representative and PI for TIPs;
- D. making the appropriate changes to the Revision History section of the procedure;
- E. updating the "modification number" on each Modified page, in a sequential pattern beginning with "1"; and
- F. issuing the modified pages of the procedure to copy holders, with instructions on how to replace older pages with them, and per Section 3.4 of this procedure.

Proposed changes to a procedure after issuance of its third active modification shall initiate the revision process (Section 3.5.3). The preparer shall assure that record packages consisting of the original signed Modification Record, the modified pages as issued, review

documentation and other supporting materials are created and submitted to the YMP-LBNL Records Processing Center.

3.5.3 Revisions

Revisions to active procedures are required following issuance of a third modification to the procedure, or sooner if the changes to the procedure are substantial. They are made by:

- A. review of the historical changes to the QIP by the EA Manager, and to the TIP by the PI;
- B. renumbering all procedure pages to indicate the new revision and modification numbers. The revision number shall be one greater than the previous revision number, and the modification number shall be reset to zero. Section 9, "Revision History," of the new revision to the procedure shall also be updated, including:
 - the reason(s) for the change(s),
 - the impact (if any) upon work activities; and
 - the page numbers where change(s) have been made;
- C. completion of work steps in Sections 3.3, "Review and Approval of a Procedure," and 3.4, "Distributing a Procedure" of this procedure; and
- D. submittal of an updated input to the requirements matrix database, as appropriate, by the EA Manager (see section 3.4).

3.5.4 Expedited Change(s) to a TIP

If responsible management (i.e., person in charge of a task described in a TIP) determines that a modification (Section 3.5.2) or a revision (Section 3.5.3) to the TIP would cause an unreasonable delay in proceeding with the task, then an expedited change to the procedure (including documentation of deviation from the approved procedure) can be made. Such changes are subject to review, usually after the task has proceeded, and thus work performed under TIPs with expedited changes is done at risk of future invalidation.

The Preparer shall make expedited changes to a TIP by:

- A. attaching a memo with a description of the change(s) and justification, and making corresponding handwritten text change(s), to the local copy of the TIP;
- B. dating and initialing the handwritten change(s); and

- C. processing the change per this procedure as a modification, revision, or rescission, as soon as practical but within 10 working days. If the expedited change is found to be unacceptable, then any work performed under that expedited change is subject to technical review for acceptability under the appropriate PI's authority. The Preparer shall create a record package containing a copy of the expedited change and the resolution of the resulting review submit it to the YMP-LBNL Records Processing Center.

3.6 Rescinding a Procedure

QIPs - Any staff member may suggest the rescission of a QIP to the EA Manager. The EA Manager shall evaluate the suggestion and confer with the Project and all affected organizations. If all parties are in agreement and with OQA Representative concurrence and PM approval, the EA Manager shall rescind the procedure, justify the action in a memo to the procedure's record package, and assure that the YMP list of controlled documents is updated accordingly. The Document Control Staff shall assure that all copy holders return or destroy their copies of the rescinded document. After rescission of a QIP, the EA Manager shall process a QARD requirements matrix update in accordance with section 3.4, as appropriate.

TIPs - Any staff member may suggest the rescission of a TIP to the appropriate PI. The PI shall evaluate the suggestion and confer with the EA Manager and all affected organizations. If all parties are in agreement and with OQA Representative concurrence and PM approval, the PI shall rescind the procedure, justify the action in a memo to the procedure's record package (with a copy to the EA Manager), and assure that the YMP list of controlled documents is updated accordingly. The Document Control Staff shall assure that all copy holders return or destroy their copies of the rescinded document.

4. RECORDS MANAGEMENT

4.1 Lifetime

Final approved QIPs and TIPs, expedited changes, revisions, modification records and supporting documentation.

4.2 Non-permanent

Reviewed drafts

(see also YMP-LBNL-QIP-6.1)

4.3 Controlled Documents

QIPs

TIPs

4.4 Records Center Documents

Records associated with this procedure shall be submitted to the YMP-LBNL Records Processing Center, in accordance with YMP-LBNL-QIP-17.0 and AP-17.1Q.

5. RESPONSIBILITIES

5.1 The Project Manager is responsible for final approval of all new, revised, and modified procedures, and for final approval of the rescission of procedures.

5.2 The EA Manager is responsible for identifying, reviewing and approving all QIPs, for overseeing and coordinating preparation, review, revision, and rescission of QIPs, and preparing the QARD requirements matrix. The EA Manager is also responsible for approving all new, revised, and modified TIPs, and for the rescission of TIPs.

5.3 The OQA Representative is responsible for reviewing and concurring with all QIPs, QARD requirements matrices, and TIPs.

5.4 The Principal Investigator is responsible for overseeing and coordinating the preparation, review, distribution, revision, and rescission of TIPs, and for the related training of personnel.

5.5 Staff Members involved in the preparation or review of procedures are responsible for following this procedure and turning over related documentation to the YMP-LBNL Records Processing Center in accordance with YMP-LBNL-QIP-17.0 and AP-17.1Q.

5.6 Document Control Staff is responsible for providing the controlled distribution of procedures and modifications to them.

6. ACRONYMS AND DEFINITIONS

6.1 Acronyms

QARD Quality Assurance Requirements and Description.

QIP Quality Implementing Procedure

TIP Technical Implementing Procedure

6.2 Definitions

Management Review For the purposes of this procedure, a management review of a document is a review performed by the PM, EA Manager, or appropriate PI, to a level of detail determined by the reviewer.

A management review may range in rigor from a simple undocumented completeness check to a fully documented review per the requirements of YMP-LBNL-QIP-6.1.

QARD Requirements Matrix A system by which QARD requirements are mapped and tracked against procedures implementing the requirements, including YMP-LBNL QIPs.

Quality Implementing Procedure Each QIP describes an aspect of the YMP-LBNL implementation of YMP QARD requirements.

Staff Member Any scientist, engineer, research or technical associate, technician, or student research assistant performing quality-affecting work for YMP-LBNL.

Technical Implementing Procedure Each TIP describes YMP-LBNL technical and/or scientific tasks that (1) are repetitive, (2) are standardized, and (3) could return different results should deviation from the sequence of steps occur. TIPs are written when such tasks are sufficiently complex to warrant a formal procedure.

7. REFERENCES

AP-17.1Q, *Record Source responsibilities for Inclusionary Records*.

DOE/RW/0333P, *Quality Assurance Requirements and Description*.

YMP-LBNL-QIP-6.1, *Document Review*.

YMP-LBNL-QIP-17.0, *Submitting Records to the YMP-LBNL Records Processing Center*.

8. ATTACHMENTS

Attachment 1 - YMP-LBNL Procedure Modification Record.

9. REVISION HISTORY

10/21/96 - Revision 0, Modification 0

YMP-LBNL-QIP-5.2 issued, to supersede and replace YMP-LBNL-QIP-5.0 and YMP-LBNL-QIP-5.1.

6/2/97 - Revision 1, Modification 0

Revised procedure to introduce the term engineering assurance and to re-define position responsibilities.

10. APPROVAL

Preparer:

Date

Technical Review:

Date

Technical Review:

Date

QA Reviewer:

Date

QA Manager:

Date

Project Manager:

Date

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